UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,786	02/20/2004	David M. Kranz	89-99A	7830

23713 7590 10/10/2006

GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,786	KRANZ ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 25-37, 50-55, 82 and 83, drawn to a method for using high affinity TCRs to identify ligands and a method of binding a high affinity TRC to a cell carrying a selected peptide/MHC ligand, classified in class 435, subclass 7.1.

II. Claims 11, 38-43 and 80-81, drawn to a method for blocking autoimmune destruction of cells and a pharmaceutical composition comprising a high affinity TCR, classified in class 424, subclass 185.1.

III. Claims 12, 44-49, 70-71, 74, 75 and 80-81, drawn to a method for using high affinity TCRs coupled to a therapeutic compound to treat cancer or kill an undesirable cell and a pharmaceutical composition comprising a high affinity TCR, classified in class 514, subclass 2.

IV. Claims 13-14, 72-73 and 80-81, drawn to a method for using high affinity TCRs coupled to a toxic compound to kill pathogen infected cells and a pharmaceutical composition comprising a high affinity TCR, classified in class 514, subclass 2.

V. Claims 15-18, drawn to soluble TCRs, classified in class 530, subclass 350.

VI. Claim 19, drawn to a DNA library comprising DNAs encoding high affinity TCRs, classified in class 536, subclass 23.1.

VII. Claim 20, drawn to a library of TCR proteins displayed on yeast cells, classified in class 435, subclass 254.2.

VIII. Claims 21-24, 56-63, 64-69 and 79, drawn to a method for cloning a high affinity TCR, classified in class 435, subclass 455.

IX. Claims 76-78, drawn to a method for treating disease in a patient comprising the steps of: removing wild-type T cells from the patient; transforming the T cells with the vector that expresses a high affinity TCR mutant, to express the high affinity TCR in the T cells; returning the transformed T cells to the patient; wherein the transformed T cells are activated to a greater extent than the wild type T cells of the patient, classified in class 424, subclass 93.2.

It is noted that claims 80-81 are included in Groups II-IV as the pharmaceutical compositions recited in Claims 80-81 can be used in any of the methods of Groups II-IV.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions involve unrelated processes. The different processes have different designs and are directed to patentably distinct outcomes, i.e. using TCRs to identify ligands (Group I) or block autoimmune destruction of cells (Group II) or kill neoplastic (Group III) or pathogen infected cells (Group IV) or clone high affinity TCRs

(Group (VIII) or *ex vivo* gene therapy treatment of a disease in patients (Group IX). Each Group utilizes distinct method steps and a search of one Group would not be co-extensive with a search of the others and hence would be burdensome.

Inventions V and I-IV, VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions involve a composition (soluble TCRs, Group V) while the other Groups involve processes which do not recite use of soluble TCRs. A search of the art reading on soluble TCRs would not identify art on the processes and visa versa; hence said search would be burdensome.

Inventions VI and I-IV, VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions involve a DNA library comprising DNAs encoding high affinity TCRs while the other Groups involve processes which do not recite use of a library of TCRs. The processes recite use of individual TCRs with specific binding targets and do not recite use of a DNA library of sequences encoding TCRs. A search of the art reading on a library of high affinity TCRs would not identify art on the processes and visa versa; hence said search would be burdensome.

Inventions VII and I-IV, VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant

case, the different inventions involve a library of TCR proteins displayed on the surface of yeast cells while the other Groups involve processes which do not recite use of a library of TCR proteins displayed on yeast cells. The processes recite use of individual TCRs with specific binding targets and do not recite use of a yeast library displaying TCRs on the surface of said yeast cells. A search of the art reading on a library yeast cells expressing TCRs would not identify art on the claimed processes and visa versa; hence said search would be burdensome.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM - 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David Guzo
September 30, 2006